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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/980,987 | 11/06/2001 | David Colclough | PU3611USW | 2010 |

23347 7590 03/07/2005

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| EXAMINER |
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COLEMAN, BRENDA LIBBY

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| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 03/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HCL

Office Action Summary

Application No.

09/980,987

Applicant(s)

COLCLOUGH ET AL.

Examiner

Brenda L. Coleman

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-8 and 10-12 are pending in the application.

This action is in response to applicants' amendment dated December 16, 2004.

Claims 5-8 and 10-12 have been amended.

Note: The applicants' are reminded of the manner of making amendments.

37 CFR 1.121 Manner of making amendments in application.

(c) Claims. Amendment to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims in the amendment document will serve to replace all prior versions of the claims in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

The following claims fail to properly identify the status of the claims: claims 11 and 12, i.e. (Previously amended) should be (Currently amended) or (Amended).

Response to Amendment

Applicants' arguments filed December 16, 2004 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejection labeled paragraph 1a) maintained in the last office action, which is hereby **withdrawn**.

2. With regards to the 35 U.S.C. § 103, obviousness rejection of claims 1-8 over SUGG et al., U.S. Patent No. 5,646,140 maintained in the last office action, the applicant's arguments have been fully considered but are not found persuasive. The applicants stated that "the rejection of the claims is improper" and that "[i]t is only the impermissible use of hindsight gained from Applicants' present patent application that has led the Examiner to assert the '140 patent". It is not hindsight if there is motivation. As stated in the last office action, U.S. '140 specifically discloses how to prepare seven compounds of which one is **racemate** of the applicant's compounds i.e. example 7. Example 1 discloses the process of separating the enantiomers of the racemic compounds using chiral hplc as claimed herein. U.S. '140 states in column 5, lines 30-34 that "[t]hose skilled in the art will recognize that stereocenters exist in compounds of Formula (I). Accordingly, the present invention includes all possible stereoisomers and geometric isomers of Formula (I) and includes **not only racemic compounds** but also the optically active isomers as well." U.S. '140 also states in column 12, line 67 through column 13, line 2 that "[s]pecific enantiomers of the compounds of formula (I) may be obtained by **resolution of the racemic compounds using conventional procedures such as chiral HPLC.**"

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over SUGG et al., U.S. Patent No. 5,646,140, for reasons of record and stated above.

3. With regards to the obviousness-type double patenting rejection of claims 1-8 over claims 1-4, 6-8 and 17 of U.S. Patent No. 5,646,140 maintained in the last office action, the applicant's filing of a terminal disclaimer with the response filed December 16, 2004 is acknowledged. Upon approval of this terminal disclaimer the rejection will be overcome.

Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8 and 17 of U.S. Patent No. 5,646,140, for reasons of record and stated above.

4. With regards to the obviousness-type double patenting rejection of claim 4 over claims 1-4, 6-8 and 10 of U.S. Patent No. 5,780,464 of the last office action, the applicant's stated that this rejection is moot in view of the terminal disclaimer filed with the response on December 16, 2004. There was no terminal disclaimer filed for U.S. Patent No. 5,780,464, therefore the rejection of claim for is herein maintained.

Claim 4 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8 and 10 of U.S. Patent No. 5,780,464, for reasons of record and stated above.

5. With regards to the obviousness-type double patenting rejection of claims 5-8 over claims 1-4 and 6-8 of U.S. Patent No. 5,910,495 of the last office action, the applicant's stated that this rejection is moot in view of the terminal disclaimer filed with the response on December 16, 2004. There was no terminal disclaimer filed for U.S. Patent No. 5,910,495, therefore the rejection of claim for is herein maintained.

Claims 5-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 5,646,140, for reasons of record and stated above.

6. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 9) of the last office action, which are hereby **withdrawn**.

In view of the amendment dated December 16, 2004, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 10-12 are vague and indefinite in that it is not known what is meant by nomenclature in (a) which is missing a close bracket and an open "{".

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b) Claims 10-12 are vague and indefinite in that it is not known what is meant by the definition of the variable R_1 , which is defined as hydrogen. When R_1 is hydrogen formula V is the unsubstituted phenyl carbonate as defined in (iii).

Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda L. Coleman
Primary Examiner Art Unit 1624
March 3, 2005